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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,460	12/29/2005	Etienne Pouteau	3712036.00697	6141
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K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER LAU, JONATHAN S	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 01/05/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,460	<b>Applicant(s)</b> POUTEAU ET AL.	
	<b>Examiner</b> Jonathan S. Lau	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 7-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5 and 7-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Office Action is responsive to Applicant's Amendment and Remarks, filed 26 Oct 2010, in which claims 1 and 5 are amended to change the scope and breadth of the claim, claims 7-12 are amended to change the dependency of the claim, and claims 3 and 6 are canceled.

This application is the national stage entry of PCT/EP04/07092, filed 30 Jun 2004; and claims benefit of foreign priority document EP 0301486.7, filed 30 Jun 2003. This foreign priority document is in English.

Claims 1, 4, 5 and 7-13 are pending and examined on the merits herein.

The following are modified grounds of rejection necessitated by Applicant's Amendment, filed 26 Oct 2010, in which claims 1 and 5 are amended to change the scope and breadth of the claim, claims 7-12 are amended to change the dependency of the claim, and claims 3 and 6 are canceled.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Amended Claims 1, 4, 5 and 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 recite “protein source”, “lipid source” and “carbohydrate source” (emphasis added). Claims 4 and 7-10 depend from claim 1 and incorporate all limitations therein. Claim 11 and 12 depend from claim 5 and incorporate all limitations therein. The terms “protein source”, “lipid source” and “carbohydrate source” render the claims indefinite because it is unclear what is the scope of these terms. The specification provides only non-limiting examples of proteins as a protein source (page 7, lines 5-10), fats as the lipid source (page 7, lines 10-15), and the inclusion or exclusion of monosaccharides as the carbohydrate source (page 7, lines 15-25). One of skill in the art would understand that via metabolic pathways raw materials such as glucose are used to make amino acids and proteins or used to make lipids, therefore it is unclear if said carbohydrate is a “protein source”, a “lipid source” or a “carbohydrate source”. Therefore one of ordinary skill in the art would not be readily apprised of the metes and bounds of the invention as recited in the claims.

**Response to Applicant's Remarks:**

Applicant's Remarks, filed 26 Oct 2010, have been fully considered and not found to be persuasive.

Applicant asserts that glucose is free of nitrogen and can never be converted to amino acids or proteins. Applicant remarks that a skilled artisan will appreciate that, for example, a protein source is any material that proteins may be derived from.

Art Unit: 1623

However, based on the metabolic pathways map (Metabolic Pathways, 2003, cited in PTO-892) while glucose (top of map at middle) itself does not contain nitrogen and therefore does not contain all of the individual atoms of an amino acids or proteins, it is metabolized into pyruvate (middle of map at middle), which can be converted into amino acids (bottom right corner of map) such as by action of aminases that transfer an amino group. Therefore, while glucose can never be directly converted to amino acids or proteins owing to the lack of the constituent atoms such as nitrogen, it can serve as a "source" for amino acids or proteins. Similarly, there are metabolic pathways between carbohydrates (top left corner of map) and lipids (middle left of map), such that each can serve as a "source" of the other as related through multiple metabolic steps. Further, while one example of the relationship is the metabolic conversion of compounds, the term "source" is also interpreted to encompass non-metabolic organic synthesis reactions that may be used to oxidize a long-chain alkane into a fatty acid, or lipid, for example. Therefore it is broadening term "source" that renders the terms indefinite such that it is unclear what compounds are encompassed within each term, and whether any given compound is thus a protein source, lipid source and/or carbohydrate source.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1623

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Genovese et al. (Diab. Nutr. Metab. 1992, 5, p295-297, cited in PTO-892) in view of Florent et al. (J. Clin. Invest. 1985, 75, p608-613, cited in PTO-892).

Genovese et al. teaches the administration of lactulose to non-insulin dependent diabetic patients (page 295, abstract). Genovese et al. teaches the administration results in a reduction of blood glucose after challenging with an oral glucose tolerance test (OGTT) with no significant difference in serum insulin concentration (page 296, right column, paragraphs 1-2). Genovese et al. teaches the effect is more pronounced from 90 to 180 min after the glucose load (page 296, right column, paragraphs 3) and suggests the fermentation of lactulose in the colon has some influence on blood glucose metabolism (page 296, right column, paragraphs 4-5). Genovese et al. teaches the lactulose given during meals (page 295, right column, paragraph 2).

Genovese et al. does not specifically teach the method reduces insulin resistance or administering lactulose between 3 and 7 hours before a meal (instant claim 13).

Florent et al. is drawn to the colonic metabolism of lactulose in man such as transit time of ingested lactulose to the colon (page 612, paragraph spanning bottom of left column and top of right column). Florent et al. teaches, for example, a time to lactose peak concentration at the ileum of 172 to 210 minutes (page 610, table III at top of right column).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Genovese et al. in view of Florent et al. It would have been obvious to one of ordinary skill in the art to combine the teaching of Genovese et al. to give the method of treating insulin resistance by reducing insulin resistance because Genovese et al. teaches a reduction of blood glucose with no significant difference in serum insulin concentration in non-insulin dependent diabetic patients, or patients having insulin resistance, suggesting a reduction of resistance to the same level of insulin. One of ordinary skill in the art would have been motivated to combine Genovese et al. in view of Florent et al. to administer the lactulose 172 to 210 minutes before a meal because Genovese et al. teaches the effect of the lactulose is more pronounced 90 to 180 min after the glucose load and suggests it is the fermentation of lactulose in the colon that has some influence on blood glucose metabolism, and Florent et al. teaches the transit time of ingested lactulose to the colon.

**Response to Applicant's Remarks:**

Applicant's Remarks, filed 26 Oct 2010, have been fully considered and not found to be persuasive.

Applicant notes that Genovese et al. does not teach that insulin resistance can be improved. However, the instant invention as claimed encompasses both treating and improving insulin resistance by reducing insulin resistance. Genovese et al. teaches the administration results in a reduction of blood glucose after challenging with an oral glucose tolerance test (OGTT) with no significant difference in serum insulin concentration, suggesting the treatment of insulin resistance by reducing insulin resistance.

Applicant's remarks that Florent is directed to the effects of a repeated load of a unabsorbable carbohydrate on intracolonic metabolism. Applicant notes that Florent does not teach the intracolonic metabolism of lactulose reduces insulin resistance and does not suggest a dosing regime based on said intracolonic metabolism for that purpose. However, both Genovese et al. and Florent et al. teach some delay between the administration of lactulose and metabolism of the ingested lactulose. Further, upon reconsideration of the language of the claim, it would have been obvious to one of ordinary skill in the art that the administration of lactulose is between 3 and 7 hours before "a meal" because Genovese et al. teaches administration during meals (page 295, right column, paragraph 2). It well-known to be routine in the art to eat three meals a day, that of breakfast, lunch and dinner. It would have been obvious to one of ordinary skill in the art that lactulose administered with breakfast according to Genovese et al. in view of Florent et al. is administered between 3 and 7 hours before the meal of lunch,



Art Unit: 1623

and lactulose administered with lunch is administered between 3 and 7 hours before the meal of dinner. Therefore it would have been obvious that the lactulose is administered between 3 and 7 hours before “a meal”, said meal being the subsequent meal of the day. Therefore the invention as claimed encompasses the invention taught by Genovese et al. in view of Florent et al.

### ***Conclusion***

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-

Art Unit: 1623

3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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